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Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Veterinary Services

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 01-14

Subject: Approved Sources of Animal Origin Ingredients

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

This notice informs licensees, permittees, and applicants of current Center for Veterinary Biologics (CVB) requirements concerning the source of animal origin ingredients for use in veterinary biologics.

Historically, ingredients of animal origin used in veterinary biologics are required to be in compliance with 9 CFR 113.53. Given the heightened awareness of bovine spongiform encephalopathy (BSE), and the devastating problems that would be created in this country should it be introduced, CVB will require several additional steps to ensure that ingredients of animal origin represent a minimal risk to the agriculture industry.

In addition to meeting the requirements of 9 CFR 113. 53, ingredients of animal origin should be sourced from countries whose BSE status is either no risk or low risk as defined by the National Center for Import and Export, and 9 CFR 94.18. Licensees, permittees, and applicants should develop and maintain a comprehensive list of all ingredients of animal origin used in the production of their biological products. This list should include the name of the material, the supplier, the country of origin, and the date of purchase of each lot. This list may be reviewed, and certification of materials required at the time of inspection by CVB-Inspection and Compliance, or at other times as requested by CVB.

A statement certifying that ingredients of animal origin are sourced from countries where BSE is not known to exist should be included in Section II. of each Outline of Production at the next annual review. In the interim, each licensee or permittee should submit a letter to the CVB-Licensing and Policy Development staff documenting that the products they are producing/importing, meet these requirements.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics